PATENT APPLICATION

IN THE U.S. PATENT AND TRADEMARK OFFICE

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Applicants: Junzo SUNAMOTO et al

For: COSMETIC PRODUCT CONTAINING POLYSACCHARIDE-STEROL DERIVATIVE

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Commissioner for Patents
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DECLARATION UNDER 37 CFR 1.132

I, the undersigned, hereby declare as follows:

I am one of the co-inventors of the invention described and claimed in application Serial No. 09/936 953, filed on September 17, 2001.

I hereby incorporate by reference herein the contents of the Synthesis Examples, Examples and Comparative Examples contained in application Serial No. 09/936 953.

In order to illustrate the superior properties associated with the pullulan-cholesterol derivatives of the present invention, I have conducted additional tests.

SYNTHESIS EXAMPLE A

Synthesis of pullulan-cholesterol derivative

In an eggplant type flask of 1 liter capacity, there were charged 40 grams (248 mmol as calculated based on the glucose anhydride unit) of a pullulan (a commercial product of Wako Pure Chemical Industries, Ltd. having an average molecular weight of 108,000) and 420 ml of dimethyl sulfoxide (DMSO) and the charge was agitated at 80°C under a nitrogen atmosphere

until a clear solution resulted. To this solution was added a solution prepared by dissolving 1.78 grams (3.21 mmol) of N-(6-isocyantohexyl)cholesteryl carbamate in 32.4 ml (0.40 mmol) of pyridine to cause a reaction at 90°C for 1.5 hours. After the reaction, DMSO was evaporated off under a reduced pressure, whereupon the resulting oily residue was poured into 6 liters of acetone to effect purification by reprecipitation. The resulting precipitate was collected by decantation and subsequent vacuum filtration, before it was dissolved again in DMSO and the resulting solution was subjected to dialysis against distilled water to attain purification thereof.

The degree of introduction of cholesteryl group in the pullulan skeleton was estimated from the NMR spectrum data to be 1.3 groups per 100 monosaccharide units. This product was referred to as CHP1.

In the same manner as above, products CHP2 to CHP4 were synthesized using varying charge proportion of N-(6-isocyanatohexyl)cholesteryl carbamate. The detected degrees of introduction of cholesteryl groups into the pullulan skeleton were as given below:

Cholesteryl group introduction degree

CHP1: 1.3 groups per 100 monosaccharide units
CHP2: 2.1 groups per 100 monosaccharide units
CHP3: 3.2 groups per 100 monosaccharide units
CHP4: 3.9 groups per 100 monosaccharide units

EXAMPLE A

Preparation of beauty wash and assessment test

A base beauty wash was prepared by mixing 77 parts by weight of pure water, 12 parts by weight of glycerin, 6 parts by weight of 1,3-butanediol and 5 parts by weight of ethanol with sufficient agitation, whereto one of the above CHP1 to CHP4 and a pullulan each was admixed in an amount of one percent by weight to formulate each sample of beauty wash.

Five volunteers of 28-57 years old were tested by treating each volunteer by applying each sample over each of 6 specific skin areas on an inner side of both forearms four

times a day at a periodic interval of two hours, whereupon the elastic performance of the skin (performance for elastic recovery from forced deformation) for each specific area was observed using Cutometer SEM474 (an apparatus made by the firm Courage+Khazaka) for the initial value and for the value after two days. The results of the test as given in a value averaged over the five volunteers indicated that the elastic recovery performance of skin increased by applying the products CHP1 to CHP4 to the skin as compared with the cases where no treatment of skin was incorporated and where the skin was treated with the sample containing the pullulan. The results are shown in Table A.

Method of determination of the elastic performance of the skin:

1. Method of Experiment

A probe is impressed on a specific skin area on an inner side of the forearm, whereupon the internal pressure inside the probe is reduced so as to cause the skin area to swell up. The magnitude of swelling deformation of the skin is observed optically at a unit of 0.01 mm.

Then, the reduced pressure is relieved gradually up to 0 hPa while observing the magnitude of skin level reducing movement.

2. Apparatus, Condition and Environment of determination

2.1 Determination Apparatus:

Cutometer SEM 474 (made by the firm Courage+Khazaka)

2.2 Determination Condition:

Inner diameter of the probe: 2mm; Determination mode: P mode; Maximum reduced pressure: 300 hPa; Time for reducing the internal pressure: 10 seconds; Time for relieving the reduced pressure: 10 seconds

2.3 Environment of Determination:

Temperature: 20°C; Relative humidity: 40%

3. Method of Calculation of Elastic Recovery Performance

The elastic performance of skin, namely, the elastic recovery performance of skin, is calculated by the equation

Elastic recovery performance % = [(A-B)/A] × 100 where A is the maximum value of the observed height of the swelled skin upon reduction of the inner pressure inside the probe and B is the observed value of the skin level height after relief of the inner pressure.

RESULTS

TABLE A Elastic Performance of Skin

Sample of beauty wash with	Elastic recovery performance		Relative performance value	
	Initial	After 2 days	Initial	After 2 days
No addition	78.5%	79.2%	1.000	1.009
CHP1	77.2%	82.5%	1.000	1.069
CHP2	79.2%	84.1%	1.000	1.062
CHP3	76.8%	81.1%	1.000	1.056
CHP4	77.8%	83.6%	1.000	1.075
Pullulan	79.6%	80.8%	1.000	1.015

DISCUSSION OF RESULTS

As can be seen by the results contained in Table A, the pullulan-cholesterol cosmetic compositions of the present invention unexpectedly improve the elasticity of human skin as compared with the cosmetic compositions containing pullulan instead of the inventive pullulan-cholesterol derivative or not containing a polysaccharide at all.

I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Dated: March 12, 2007

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